K130744

COVIDIEN

APR 0 5 2013

510(k) Summary

Date summary prepared: 3/18/2013

510(k) Submitter/Holder

Covidien
5920 Longbow Drive
Boulder, CO 80301

Contact

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Name of Device

Trade Name:	LigaSure™ 5 mm Blunt Tip Laparoscopic Sealer/Divider
Catalog Number:	LF1637
Common Name:	Bipolar Electrosurgical Instrument
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR § 878.4400, class II, GEI).

Predicate Device

The LigaSure™ 5 mm Blunt Tip Laparoscopic Sealer/Divider (LF1637) was compared to and found to be substantially equivalent to the following product of comparable type in commercial distribution:

Trade Name:	LigaSure™ 5 mm Blunt Tip Laparoscopic Sealer/Divider
Device Common Name:	Bipolar Electrosurgical Instrument
Catalog Number:	LF1537
510(k) Number:	K092879 (cleared 10/16/2009)
Manufacturer:	Covidien

Device Description

The LigaSure™ 5 mm Blunt Tip Laparoscopic Sealer/Divider (LF1637) is a sterile, single-use, hand-held bipolar electrosurgical instrument designed exclusively for use with the ForceTriad™ energy platform (generator) to ligate (seal) and divide (cut) vessels, tissue bundles, and lymphatics clamped between the jaws, grasping tissue, and blunt dissection during laparoscopic general surgical procedures (as indicated) using radio frequency (RF) energy. A hand actuated lever allows the user to open and close the instrument jaws, and includes a latching mechanism that holds the jaws in the closed position during vessel sealing and cutting.

Indications for Use

The LF1637 LigaSure 5 mm, Blunt Tip, Laparoscopic Sealer/Divider is a bipolar electrosurgical instrument intended for use with the ForceTriad Energy Platform in general and gynecologic laparoscopic surgical procedures where ligation and division of vessels and lymph is desired. The instrument creates a seal by application of RF electrosurgical energy to vascular structures (vessels and lymph) interposed between the jaws of the instrument. A blade within the instrument is surgeon actuated to divide tissue.

Indications for use include general laparoscopic procedures including urologic, vascular, thoracic and thoracoscopic, and gynecologic procedures where ligation and division of the vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, colectomy, adhesiolysis, oophorecotmy, etc. The device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

The LigaSure 5 mm Blunt Tip Laparoscopic Sealer/Divider can be used on vessels and lymphatics up to and including 7 mm, and tissue bundles.

Technological Characteristics

The LigaSure 5 mm, Blunt Tip, Laparoscopic Sealer/Divider has the same technological and performance characteristics as the predicate, K092879. This Special 510(k) presents proposed modifications relating to the jaw, handle, and component material changes. The function of the device has not changed. Similar to the predicate, this new device seals vessels and lymphatics using radio frequency (RF) energy to achieve its intended use and can mechanically divide the sealed areas or tissue with a mechanical cutting device.

Performance

Evidence of safety and effectiveness was obtained from both bench and preclinical testing. Bench testing to support the intended use of this device includes:

- Testing in accordance with IEC 60601-1
- Testing in accordance with IEC 60601-2-2
- Mechanical testing such as blade return, grasping performance, jaw temperature, jaw force, button activation force, knife deployment force, lever latching/unlatching force, and power curve performance
- Renal and pulmonary burst pressure

Preclinical testing includes:

- Sealing and dividing vessels up to and including 7 mm
- Ability to achieve hemostasis of tissue and vessels
- Lymphatic burst pressure
- Chronic animal study

The results of the testing demonstrate that the proposed device, the LF1637, operated as intended and is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Covidien
% Ms. Diane Reed
Senior Regulatory Affairs Product Specialist
5920 Longbow Drive
Boulder, Colorado 80301

Letter dated: April 5, 2013

Re: K130744
Trade/Device Name: LigaSure™ 5mm Blunt Tip Laparoscopic Sealer/Divider
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 18, 2013
Received: March 19, 2013

Dear Ms. Reed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K130744

Device Name: LigaSure™ 5 mm Blunt Tip Laparoscopic Sealer/Divider (LF1637)

Indications for Use:

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Prescription Use (Part 21 CFR 801 Subpart D)	✓	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)		

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA Joshua C. Nipper -S

For

(Division Sign-Off)

Division of Surgical Devices

510(k) Number K130744